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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF :
Yoshio HIRAKI et al : GROUP ART UNIT: 1617
SERIAL NO.: 09/913,721 : EXAMINER: Gina YU
FILED: August 17, 2001 :
FOR: SKIN PREPARATIONS FOR EXTERNAL USE

REPLY BRIEF

COMMISSIONER FOR PATENTS
ALEXANDRIA, VIRGINIA 22313

SIR:

In the Response to Argument section on page 5 of the Examiner's Answer the
Examiner states:

“While Applicants’ argue that the presence of cholesterol in a lamellar vesicle composition as taught by Mathur would change the basic and novel characteristics of the claimed invention, the presently claimed lamellar structure nonetheless requires cholesterol also.”

However, the argument made in the Appeal Brief was not that the present claims exclude cholesterol, but that they include a secondary lipid different from the primary lipid and preferably from those set forth in column 2, lines 37-43, which include lipids, such as, quaternary dimethyldiacylamines, including ammonium derivatives such as chlorides, polyoxyethylene acyl alcohols, polyglycerols, fatty acids, and sorbitan fatty acid esters. The addition of cholesterol is discussed in Mathur et al in column 3, line 66 through column 4, line 14 and clearly indicates that Mathur et al does not consider cholesterol a secondary lipid, but only as an additive to aid in the formation of a lamellar phase, which can then be formed

into a lamellar vesicle, because of the pressure of the secondary lipid, discussed above.

Cholesterol is also discussed in the present specification only as an aid for improving the stability of the lamellar structure on page 4 of the present specification and, therefore, does not fall into the category of a secondary lipid, as disclosed in Mathur et al.

The Examiner argues on pages 5 and 6 of the Examiner's Answer that there is no clear indication either in the specification or claims that the basic and novel characteristic of the claimed invention is using mono fatty acid monoglyceride as the only lipid in the lamellar composition and cites the fact that cholesterol is used in every single example formulation of the specification. However, it is clear from a reading of the present specification and Mathur et al., discussed above, that cholesterol is only a stabilizing additive in both Mathur et al and the present specification and cannot be considered a secondary lipid, as disclosed in Mathur et al., which secondary lipid is critical for the formation of the lamellar vesicles of Mathur et al. and unnecessary for the formation of the lamellar structure of the present claims.

The Examiner further notes on page 6 of the Examiner's Answer that either monostearyl or monopalmityl glyceryl ether is used in compositions of the present specification. However, neither monostearyl or monopalmityl glyceryl ether may be considered a secondary lipid, since the monostearyl and monopalmityl moiety is part of an ether moiety and the remaining moieties of the glyceryl compound are hydroxyl groups and not ester group(s) found in lipids. Therefore, the above-recited ethers cannot be considered secondary lipids like those described in Mathur et al.

The Examiner further states that Applicants' argument that the reference teaches away from the composition of the present claims is erroneous and there is no teaching in Mathur et al., either express or implied, to teach away from the present invention. However, as stated above and in the Appeal Brief, it is Applicants' position that Mathur et al teaches away from

the invention of the present claims, because the present claims contain the exclusionary language "consisting essentially of", which clearly excludes the addition of a secondary lipid that would change the essential nature of the composition of the present claims.

The Examiner further states that Applicants' remark that the Mathur et al composition in column 4 is not used as a carrier for a skin preparation is also incorrect and does not address the issue in this case, because the prior art is directed to a cosmetic formulation and the present invention is also directed to a cosmetic composition. However, it is clear that the recitation in column 3, line 66 through column 4, line 14 in which cholesterol is used with a primary lipid to form a lamellar phase does not disclose a composition used as a cosmetic, because a secondary lipid must be present in order to allow the lamellar phase to be formed into a lamellar structure, i.e., a vesicle, which vesicle carries the cosmetic material and forms a skin preparation like that of the present claims. Thus, it is clear that a lamellar phase cannot be considered a lamellar structure.

Finally, the Examiner's citation of Mathur et al as teaching the formation of a lamellar vesicle by blending a carrier containing retinoic acid into the lipophilic phase containing glyceryl distearate, cholesterol and dimethylstearyl ammonium chloride, followed by hydrating the mixture clearly supports Applicants' statement that Mathur et al teaches away from the skin preparation of the present claims, because dimethyl distearyl ammonium chloride clearly falls under the category of secondary lipid, as described in column 2, lines 37-43 of Mathur et al and a lamellar vesicle is formed by the combination, not a lamellar phase. Therefore, for the above-discussed reasons, Mathur et al teaches away from the skin preparation composition of the present claims.

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Reply to Examiner's Answer of January 28, 2004

In view of the preceding arguments, Appellants respectfully request that the Examiner's rejection of Claims 1-13 be reversed.

Respectfully submitted,

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